1. **FDA MEDICAL EQUIPMENT RECALLS AND ALERTS**. The following recalls are reported in accordance with AFMLL 2-95, page CE-4, and should be treated as directed modifications in accordance with that AFMLL and AFI 41-201, Chapter 2, Section D. If you possess any of these items and have not received recall notification, you should contact the manufacturer for recall instructions. Suspension is only required for Class I items. **(FOM-P, Capt Paul J. Toth, DSN 343-7445)**

CLASS I RECALLS: None.

CLASS II RECALLS:

6515 NS

MDC 11232	**Dialyzer, Hemodialysis**
PRODUCT	Dialyzer Control: a) Centrysystem 3 Catalog Nos.: 333103-001 - US 115v Centrysystem 3, BPM 333103-101 - US 115v Centrysystem 3 Single Needle, BPM 333103-121 - Euro 240v Centrysystem 3, Single Needle, BPM 333103-201 - US 115v Centrysystem 3+, BPM 333103-301 - US 115v Centrysystem 3+, Single Needle, BPM 333104-001 - US 115v Centrysystem 3, No Options 333104-101 - US 115v Centrysystem 3, Single Needle 333104-121 - Euro 240v Centrysystem 3, Single Needle 333104-201 - US 115v Centrysystem 3+, No Options; b) Spare Transducer Assembly Catalog numbers: 501036-000 - Arterial/Venous Pressure Transducer Spare Assembly 501212-003 - Cartridge Holder Spare Assembly 501249-220 - Transducer Connector Spare Assembly. Recall #Z-064/065-0.
CODE	a) All devices manufactured after 11/01/1998, and all devices repaired with affected spares assemblies that were shipped after 11/01/1998. Includes machine serial numbers 3C39644 through 3C42411 (with exclusion of 460 devices within that range but released prior to 11/01/1998). b) Lot numbers with prefix 11C, 12C, 01D, 02D, 03D, 04D, 05D, 06D.
MANUFACTURER	Gambro Renal Care Products, Lakewood, Colorado.
RECALLED BY	Manufacturer, by letter on August 24, 1999. Firm-initiated field correction ongoing.
DISTRIBUTION	Nationwide and international.
QUANTITY	1,442 of the affected machines are in US distribution and 307 were shipped to international distributors. Also, 204 Transducer Spare Kits , 133 Cartridge Holder Spare Kits, and 3 Transducer Connector Spare Kits were distributed domestically. International distribution of these kits was 108, 8, and 0, respectively.
REASON	The dialyzer alarm does not sound when the Maximum Arterial Pressure Alarm Limit is challenged. [ ] None Present [ ] Action Taken _____ _____

6525 NS

MDC 13281	**Computers, Radiotherapy Planning System**
PRODUCTS	Nucletron Plato External Beam Planning Radiation Therapy Software V2.1.2 and MLC/Shape Software Module V2.3 Recall #Z-038-0.
CODE	Plato RTS software version V2.1.2 used with software module

	MLC/Shape version V2.3.
MANUFACTURER	Nucletron BV, The Netherlands.
RECALLED BY	Nucletron Corporation, Columbia, Maryland, by letter and customer information bulletin sent on August 10, 1999. Firm-initiated field correction ongoing.
DISTRIBUTION	Ohio and Mexico.
QUANTITY	31 copies of software were distributed.
REASON	Coordinates for radiation beam used in therapy are mislabeled in software.
	[ ] None Present
	[ ] Action Taken _____

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6525 NS
MDC 13281 **Computers, Radiotherapy Planning System**

PRODUCTS	Plato Brachytherapy Treatment Planning System. Recall #Z-039-0.
CODE	Plato BPS Software Version 13.2 and higher.
MANUFACTURER	Nucletron BV, The Netherlands.
RECALLED BY	Nucletron Corporation, Columbia, Maryland, by letter on June 15, 1999. Firm-initiated field correction ongoing.
DISTRIBUTION	Nationwide.
QUANTITY	100 copies of software were distributed.
REASON	Software implementation error.
	[ ] None Present
	[ ] Action Taken _____

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CLASS III RECALLS:

UPDATE **The following two recalls which appeared in the October 6, 1999 Enforcement Report were re-classified from Class II to Class III recalls and should read as follows:**

6515 NS
MDC 16333 **Dosimeters**

PRODUCT	Model 35040 Keithley Therapy Dosimeter, intended use for calibration of dosimetry of therapeutic radiation treatment machine for high-energy accelerators, cobalt 60, and brachytherapy equipment. Recall #Z-1261-9.
CODE	Serial Numbers: 69450-69469; 80276-80295; 82666-82685; 81909-81928; and 86087-86106.
MANUFACTURER	Inovision Radiation Measurements, Cleveland, Ohio.
RECALLED BY	Manufacturer, by letters on July 8, 1999, and September 10, 1999. Firm-initiated field correction ongoing.
DISTRIBUTION	Nationwide and international.
QUANTITY	89 units.
REASON	A 1.6 Amp fuse may have been installed where a 1 Amp is specified.
	[ ] None Present
	[ ] Action Taken _____

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6515 NS
MDC 16333 **Dosimeters**

PRODUCT	The Tracker Display Model #35360A is sold with the Detector Model #35300A and marketed together as the Keithley Model #90100 Tracker System, a radiation measurement system intended for use

	in quality assurance programs for high energy accelerators, and cobalt 60 machines. Recall #Z-1262-9.
CODE	Serial Numbers: 83728-83747 and 84582-84601.
MANUFACTURER	Inovision Radiation Measurements, Cleveland, Ohio.
RECALLED BY	Manufacturer, by letters on July 8, 1999, and September 10, 1999. Firm-initiated field correction ongoing.
DISTRIBUTION	Nationwide and international.
QUANTITY	40 units.
REASON	A 1.6 Amp fuse may have been installed where a 1 Amp is specified. [ ] None Present [ ] Action Taken _____ _____

2. DRUG/SUPPLY PRODUCT RECALLS AND MEDICAL INFORMATION. The Food and Drug Administration (FDA) advises that the drug products listed below were recalled by the manufacturers or distributors concerned. The FDA has classified these recalls as follows:

CLASS I: A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.

CLASS II: A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

CLASS III: A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences.

Most of these items are nonstandard, and the possibility exists that medical activities may have purchased them locally. There is also a possibility that some of these items have NSNs assigned and may have been reported in earlier Q.A. messages. Activities having quantities of these items on hand will immediately suspend the materiel from issue and use. **CONUS** activities will contact the nearest office of the respective manufacturer or distributor for disposition instructions. **OVERSEAS** activities will report quantities suspended to AFMLO/FOM-P no later than **14 January 00** for disposition instructions. They should include nomenclature; lot number; manufacturer; quantity suspended; strength size; requisition; and DSCP purchase order number, contract number, and stock record account number (SRAN). (FOM-P**), Bonnie Phillips DSN (343-4170)**

CLASS I RECALLS:

NSN	**6505 Nonstandard**
PRODUCTS	a) Penicillin G Potassium for Injection, 20 Million Units, 100 mL vial, Rx bactericidal for IM or IV use. b) Cefuroxime Sodium, USP, Sterile, 1.5 grams, 20 mL vial, Rx semi-synthetic broad spectrum cephalosporin antibiotic for IM or IV use c) Cefuroxime Sodium, USP, Sterile, 750 mg, 10 mL vial, Rx semi-synthetic broad spectrum cephalosporin antibiotic for IM or IV use. d) Cefazolin Sodium, USP, Sterile, 1 gram, 10 mL vial, Rx semi-synthetic cephalosporin for IM or IV use e) Ampicillin Sodium, USP, Sterile, 250 mg, 6 mL vial, Rx synthetic penicillin for IM or IV use f) Ampicillin Sodium, USP, Sterile, 500 mg, 6 mL vial, Rx synthetic penicillin for IM or IV use g) Oxacillin Sodium for Injection, USP, 10 grams, 100 mL vial, Rx penicillinase-resistant, acid resistant, semi-synthetic penicillin. Recall #D-050/056-0.
CODE	a) Lot #9801015 (Control #8M12221) EXP 12/01 NDC 0209-8580-22 b) Lot #9806019 (Control #8E02475) EXP. 00 MA

c) Lot #9810030 (Control #8J02600) EXP 09/2000 NDC 0209-1132-22
d) Lot#9902058 (Control #9A12836) EXP 01/01 NDC 0209-0900-20
Lot #9902059 (Control #9A12837) EXP 01/01 NDC 0209-0900-20
Lot #9805020 (Control #8D02403) EXP 04/2000 NDC 0209-1000-42
e) Lot #9902054A (Control #9A12833) EXP 01 JA
Lot #9902054B (Control #9A22834) EXP 01/2002 NDC 0209-0100-22
f) Lot #9902053A (Control #9A12831) EXP 01 JA
Lot #9902053B (Control #9A22832) EXP 01/2002 NDC 0209-0150-22
g) Lot #9704019 (Control #7D01760) EXP 04/00 NDC 0209-8300-52
Note: All products are identified on the label by the Control Number. The firm's lot number does not appear on the label.

MANUFACTURER: Marsam Pharmaceuticals, Inc., Cherry Hill, New Jersey.

RECALLED BY: Manufacturer, by letter dated July 7, 1999. Firm-initiated recall ongoing.

DISTRIBUTION: Nationwide and Canada.

QUANTITY: The following amounts per lot were distributed:
Penicillin: Lot# 9801015 (Control No. 8M12221)
2,523 trays, 10 vials per tray
Cefuroxime Sodium: Lot# 9806019 (Control #8E02475)
3,512 trays, 10 vials per tray
Lot# 9810030 (Control #8J02600)
1,286 trays, 10 vials per tray
Cefazolin Sodium: Lot#9902058 (Control #9A12836)
4,661 trays, 25 vials per tray
Lot#9902059 (Control #9A12837)
5,124 trays, 25 vials per tray (note: 3 trays are on hand at the firm's distribution center in Brewster, NY)
Lot# 9805020 (Control No. 8D02403) - 6,040 trays, 10 vials per tray
Ampicillin Sodium: Lot# 9902054A (Control No. 9A12833)
1,280 trays, 10 vials per tray
Lot# 9902054B (Control No. 9A22834) - 9,576 trays, 10 vials per tray (Note: this lot was shipped from Marsam to their distribution center in Brewster, NY and is on hand at that facility).
Lot# 9902053A (Control No. 9A12831) - 2,201trays, 10 vials per tray
Lot# 9902053B (Control No. 9A22832) - 8,910 trays, 10 vials per tray (note: 7,315 trays are on hand at the firm's distribution center in Brewster, NY).
Oxacillin: Lot# 9704019 (Control No. 7D01760) - 445 trays, 10 vials per tray.

REASON: Microbial contamination revealed during initial sterility testing (at release).
[ ] None Present
[ ] Action Taken _____
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CLASS II RECALLS:

NSN **6505 Nonstandard**

PRODUCTS: Nafcillin Sodium for Injection, USP, in 100 mL vial, Rx intended for preparing IV admixtures only.
NDC #0209-7250-52. Recall #D-013-0.

CODE: Lot # 9711018 (Control # 7K02124), EXP 10/2000.

MANUFACTURER: Marsam Pharmaceuticals, Inc., Cherry Hill, New Jersey.

RECALLED BY: Manufacturer, by letter dated April 8, 1999. Firm-initiated recall ongoing.

DISTRIBUTION: Nationwide.

QUANTITY	613 trays (10 vials per tray) were distributed.
REASON	Failure to meet particle size specification. [ ] None Present [ ] Action Taken _____ _____

NSN	**6505 Nonstandard**
PRODUCTS	Various Rx drugs, some multiple potencies. Products were packaged/labeled under various labels which included Marsam Pharmaceuticals, Cherry Hill, NJ label, Schein Canada label, Marsam Canada label (batches made in 1996), Schein Pharmaceutical, Florham Park, NJ label, Apothecon label, VHA label, and Agvar Chemical label as specified below: Ampicillin Sodium, USP, Sterile, 10 gram vial Ampicillin Sodium, USP, Sterile, 2 gram vial Ampicillin Sodium, USP, Sterile, 1 gram vial Ampicillin Sodium, USP, Sterile, 500mg vial Ampicillin Sodium, USP, Sterile, 250 gram vial Ampicillin Sodium, USP, Sterile, 125 gram vial Cefaclor Capsules, USP, 250 mg Cefaclor Capsules, USP, 500mg Cefaclor for Oral Suspension, USP 125 mg Cefaclor for Oral Suspension, USP 187 mg Cefaclor for Oral Suspension, USP 250 mg Cefaclor for Oral Suspension, USP 375 mg Cefazolin Sodium, USP, Sterile, 20 gram Cefazolin Sodium, USP, Sterile, 10 gram Cefazolin Sodium, USP, Sterile, 1 gram Cefazolin Sodium, USP, Sterile, 500 mg Cerfuroxime Sodium, USP, Sterile, 7.5 grams Cerfuroxime Sodium, USP, Sterile, 1.5 grams Cerfuroxime Sodium, USP, Sterile, 750 mg Isoflurane USP , 99.9 %, 100 and 250 mL bottles Nafcillin Sodium for Injection, USP, 10 gram Nafcillin Sodium for Injection, USP, 2 gram Nafcillin Sodium for Injection, USP, 4 gram Nafcillin Sodium for Injection, USP, 1 gram Nafcillin Sodium for Injection, USP, 500 mg Oxacillin Sodium for Injection, USP, 10 gram Oxacillin Sodium for Injection, USP, 2 gram Oxacillin Sodium for Injection, USP, 1 gram Oxacillin Sodium for Injection, USP, 500 mg Penicillin G Potassium for Injection, USP, 20 million units Penicillin G Potassium for Injection, USP, 10 million units Penicillin G Potassium for Injection, USP, 5 million units Penicillin G Potassium for Injection, USP, 1 million units Penicillin G Sodium for Injection, USP, 10 million units Penicillin G sodium for Injection, USP, 5 million units Penicillin G Sodium for Injection, USP, 1 million units. Recall #D-014/049-0.
CODE	All lots with expiration date.
MANUFACTURER	Marsam Pharmaceuticals, Inc., Cherry Hill, New Jersey.
RECALLED BY	Manufacturer, by letters dated July 15, 19, 21 1999, and August 17, 1999. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide and Canada.
QUANTITY	Undetermined.
REASON	Current good manufacturing practice deviations. [ ] None Present [ ] Action Taken _____

NSN	**6505 Nonstandard**
PRODUCT	Red Blood Cells. Recall #B-047-0.
CODE	Unit #3008296.
MANUFACTURER	Wellmont Health System, doing business as Bristol Regional Medical Center, Bristol, Tennessee.
RECALLED BY	Manufacturer, by letter dated September 14, 1999. Firm-initiated recall ongoing.
DISTRIBUTION	North Carolina.
QUANTITY	1 unit was distributed.
REASON	Blood product was collected from a donor who reported travel to an area designated as endemic for malaria. [ ] None Present [ ] Action Taken _____

NSN	**6515 Nonstandard**
PRODUCT	Locking Blot Measuring Device, used to determine the required length of the locking bolt: a) Part number 357.792; b) and Part number 357.113.311. Recall #Z-075/076-0.
CODE	Lot numbers: a) A4GG415; b) lot A4GF199.
MANUFACTURER	Synthes USA, West Chester, Pennsylvania.
RECALLED BY	Synthes USA, Paoli, Pennsylvania, by E-mail on November 7, 1997. Firm-initiated recall complete.
DISTRIBUTION	Arkansas, Florida, Minnesota, North Carolina, New Jersey, Pennsylvania, Germany.
QUANTITY	22 units were distributed.
REASON	The ball that attaches to the measuring slider of the device may detach. [ ] None Present [ ] Action Taken _____

NSN	**6540 Nonstandard**
PRODUCT	Soflex UV-Absorbing Silicone PC Intraocular Lenses Model: LI51U & LI61U. Recall #Z-066/067-0.
CODE	Lot Numbers 390T, 4BG1, 4BG7, 4CRA and 4DV1.
MANUFACTURER	Bausch and Lomb Surgical, Clearwater, Florida.
RECALLED BY	Manufacturer, by letter on September 14, 1999. Firm-initiated recall ongoing..

DISTRIBUTION Nationwide.
QUANTITY 252 lenses were distributed; firm estimated that 124 units remained on market at time of recall initiation.
[ ] None Present
[ ] Action Taken _____

NSN **6540 Nonstandard**
PRODUCT LifeStyle MV2 Multifocal, Hydrophilic, Sterile Contact Lenses in blister packs, Rx product. Recall #Z-073-0.
CODE All lots.
MANUFACTURER St. Shine Optical Company, Ltd., Taiwan, Republic of China.
RECALLED BY The LifeStyle Company, Inc., Morganville, New Jersey, by letter dated August 30, 1999. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY Approximately 147,840 units were distributed.
REASON The contact lenses contain sorbic acid that is not declared on the labeling and may cause a burning sensation in the patient's eye.
[ ] None Present
[ ] Action Taken _____

CLASS III RECALLS:

NSN **6505 Nonstandard**
PRODUCTS Nafcillin Sodium for Injection, Rx semi-synthetic penicillin derived from the penicillin nucleus for IM or IV administration:
a) Nafcillin Sodium for Injection, USP, 500 mg, 6 mL vial, Control/Lot No. 7L02199
b) Nafcillin Sodium for Injection, USP, 1g, 20 and 100 mL vials;
c) Nafcillin Sodium for Injection, USP, 2g, 20 and 100 mL vials;
d) Nafcillin Sodium for Injection, USP,10g, 100 mL vial, 4 lot numbers
e) Ampicillin Sodium, USP Sterile, 1g, 10mL vial, Rx synthetic penicillin indicated for treatment of moderately severe and severe infections caused by susceptible strains of numerous (mostly gram-positive, but also specific gram-negative) organisms for IM or IV administration;
f) Cefazolin Sodium, USP, Sterile, 1 gram, 10 mL vial, Rx a semi-synthetic cephalosporin for IM or IV administration and is indicated in the treatment of serious infections.
Recall #D-005/010-0.
CODE Nafcillin Sodium for Injection:
Lot # 9712026 (Control # 7L02199), EXP 11/2000- NDC 0209-6900-22
Lot # 9701040 (Control # 7A01645), EXP 01/2000-NDC 0209-6950-22
Lot # 9710018 (Control # 7J02067), EXP 09/2000- NDC 0209-6950-22
Lot # 9712024 (Control # 7L02191), EXP 11/2000- NDC 0209-6950-22
Lot # 9711030 (Control # 7K02143), EXP 10/2000- NDC 0209-6950-22
Lot # 9710049 (Control # 7J02100), EXP 09/2000- NDC 0209-7000-42
Lot # 9702001 (Control # 7B01647), EXP 02/2000- NDC 0209-7100-22
Lot # 9702002 (Control # 7B01648), EXP 02/2000- NDC 0209-7100-22
Lot # 9802031 (Control # 8A12261), EXP 01/01- NDC 0209-7100-22
Lot # 9711015 (Control # 7K02121), EXP 10/2000- NDC 0209-7150-42
Lot # 9701037 (Control # 7A01643), EXP 01/2000- NDC 0209-7250-52
Lot # 9701038 (Control # 7A01644), EXP 01/2000- NDC 0209-7250-52
Lot # 9703050 (Control # 7C01722), EXP 03/2000- NDC 0209-7250-52
Lot # 9711019 (Control # 7K02125), EXP 10/2000- NDC 0209-7250-52.
Ampicillin Sodium:

	Lot #9809031 (Control #8H12564) EXP 08/01- NDC 0209-0250-22; Lot #9807019 (Control #8F02494) EXP 00 JN- no NDC number Lot #9806017 (Control #8E02493) EXP 00 MA- no NDC number Cefazolin Sodium: Lot #9806023 (Control #8E02431) EXP 05/2000 - NDC 0209-0900-24 Lot #9705027 (Control #7E91814) EXP 05/99- NDC 0209-1000-42 (Note: the Control Number identifies All products on the label. The firm's lot number does not appear on the label).
MANUFACTURER	Marsam Pharmaceuticals, Inc., Cherry Hill, New Jersey.
RECALLED BY	Manufacturer, by letter sent on June 6, 1999. Firm-initiated recall ongoing.
DISTRIBUTION	(a-d) Nationwide; e) Canada; f) Nationwide.
QUANTITY	The following amounts of Nafcillin Sodium for Injection, USP (per lot) were distributed: Lot # 9712026- 1,981 trays, 10 vials per tray Lot # 9701040- 3,268 trays, 10 vials per tray Lot # 9710018- 2,100 trays, 10 vials per tray Lot # 9712024- 2,184 trays, 10 vials per tray Lot # 9711030- 2,193 trays, 10 vials per tray Lot # 9710049- 951 trays, 10 vials per tray Lot # 9702001- 1,051 trays, 10 vials per tray Lot # 9702002- 2,585 trays, 10 vials per tray Lot # 9802031- 2,814 trays, 10 vials per tray Lot # 9711015- 1,055 trays, 10 vials per tray Lot # 9701037- 585 trays, 10 vials per tray Lot # 9701038- 573 trays, 10 vials per tray Lot # 9703050- 475 trays, 10 vials per tray Lot # 9711019- 602 trays, 10 vials per tray The following amounts of Sterile Ampicillin Sodium, USP (per lot) were distributed: Lot # 9809031- 5,093 trays, 10 vials per tray Lot # 9807019- 6,264 trays, 10 vials per tray Lot # 9806017- 6,000 trays, 10 vials per tray The following amounts of Sterile Cefazolin Sodium, USP (per lot) were distributed to consignees: Lot # 9806023- 4,846 trays, 25 vials per tray **Note: this lot was distributed to Schein Pharm., Brewster, NY only. Not yet distributed to customers. Lot # 9705027- 2,299 trays, 10 vials per tray.
REASON	Unapproved (ANDA) raw material assay calculations (averaging). [ ] None Present [ ] Action Taken _____

NSN	**6505 Nonstandard**
PRODUCTS	Sterile Cefazolin Sodium, USP, sterile, Rx semi-synthetic cephalosporin for IM or IV administration and is indicated in the treatment of serious infections: a) 1 gram in 10 mL vial; b) 10 gram, in 100 ml vial. Recall #D-011/012-0.
CODE	a) Lot # 9706054 (Control #7F91884) EXP 06/99, NDC 0209-0900-24; b) Lot #9705035 (Control # 7E91833) EXP 05/99, NDC 0209-1100-52. (Note: the Control Number identifies All products on the label. The firm's lot Number does not appear on the label).
MANUFACTURER	Marsam Pharmaceuticals, Inc., Cherry Hill, New Jersey.
RECALLED BY	Manufacturer, by letter dated May 3, 1999. Firm-initiated recall ongoing.

DISTRIBUTION	a) Nationwide; b) Massachusetts.
QUANTITY	a) 4,878 trays (25 vials per tray); b) 1,248 (10 vials per tray) were distributed.
REASON	Failure to meet pH specification. [ ] None Present [ ] Action Taken _____

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NSN	**6505 Nonstandard**
PRODUCT	Hemoglobulin, Immune Globulin Intravenous (Human), in 12 gram vials. Recall #B-039-0.
CODE	Lots 01839-00023, 01839-00012.
MANUFACTURER	ZLB Central Laboratory, Bern, Switzerland.
RECALLED BY	American Red Cross, Rosslyn, Virginia, by letter on August 20, 1999. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide.
QUANTITY	7,963 vials distributed.
REASON	Two lots of Immune Globulin Intravenous (Human), that exceeded the residual moisture specification. [ ] None Present [ ] Action Taken _____

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NSN	**6515 Nonstandard**
PRODUCTS	a) Orion Tracheostomy Care Kit with 14-16 Fr Catheter; b) TRACHEOSTOMY CARE KIT; sterile, single patient use trays; reorder #3017. Recall #Z-024/025-0.
CODE	a) Item #AH3018, Lot S9258; b) Item #3017, Lot S9241.
MANUFACTURER	Orion Life Systems, Inc., Wheeling, Illinois (trays); Jiang Su Jin Hong Corporation, Jintan City, Jiangsu, China (gauze).
RECALLED BY	Orion Life Systems, Inc., Wheeling, Illinois, by telephone on September 14, 1999, followed by fax. Firm-initiated recall ongoing.
DISTRIBUTION	New York, Tennessee, Wisconsin, Florida, Pennsylvania.
QUANTITY	3,040 kits were distributed.
REASON	Gauze may be contaminated with ETO resistant mold. [ ] None Present [ ] Action Taken _____

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NSN	**6515 Nonstandard**
PRODUCTS	Oxygen Pressure Regulator, Models: 3125R1GREEN, 3125R2GREEN, 8725R2BLACK, 51B2215R2, 3125R2SILVER, 8700R1GREEN, 3125L1GREEN, 51B2215L1, 3125L1GREEN, 51B2225LD1 and 51B2225L1,L106-260, L270-220/240,L370-220-A, -B, -G, -GL and -R. Recall #Z-041/059-0.
CODE	Serial numbers apply TO ALL MODEL NUMBERS: 609478 THROUGH 629904 638835 THROUGH 656842 666805 THROUGH 667644.
MANUFACTURER	Inovo, Inc., Naples, Florida.
RECALLED BY	Manufacturer, by letter faxed on September 3 and 13, 1999. Firm-initiated recall ongoing.
DISTRIBUTION	Illinois, California, Wisconsin, Utah, Arkansas, Minnesota, Indiana, Texas, Washington state, Tennessee, Pennsylvania, Missouri, Florida.
QUANTITY	4,856 regulators were distributed.

REASON	Faulty DISS fittings causing inadequate flow. [ ] None Present [ ] Action Taken _____ _____

NSN	**6515 Nonstandard**
PRODUCTS	Bacterial/Viral Filters, used to filter air/gas on mechanical ventilators and anesthesia gas machines to provide an added means of cross-contamination protection: a) Bacterial/Viral Filters, Catalogue No. 1605 b) Bacterial/Viral Filters, Catalogue No. 7178. Recall #Z-062/063-0.
CODE	a) Lot Numbers: 1-22910, 3-21910, 4-21910, and 3-29910 (for single patient use); b) Lot Numbers: 2-03910 and 3-30910 (intended only for further manufacturing).
MANUFACTURER	Hudson Respiratory Care, Inc., Temecula, California.
RECALLED BY	Manufacturer, by fax on July 27, 1999, and by letter on August 3, 1999. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide, Japan, Canada, Turkey.
QUANTITY	10,100 filters were distributed.
REASON	The filters were manufactured by ultrasonic welders that were operating out of a state-of-control causing some over-welding conditions to occur, compromising the filterís efficiency. [ ] None Present [ ] Action Taken _____ _____

NSN	**6515 Nonstandard**
PRODUCTS	Reference Electrode Disposable Membrane Caps, intended for use with the IL 1600 Series Blood Gas Analyzer. Recall #Z-035-0.
CODE	Part Number: 70987-00, Lot Numbers: 81147 EXP 11/30/99 81250 EXP 12/13/99; 90101 EXP 1/31/00 I90102 EXP 1/20/00; I90103 EXP 1/31/00 I90104 EXP 1/13/00; I90205 EXP 2/28/00.
MANUFACTURER	Instrumentation Laboratory Company, Milan, Italy.
RECALLED BY	Instrumentation Laboratory Company, Lexington, Massachusetts, by letter on September 10, 1999. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide.
QUANTITY	2,425 boxes were distributed.
REASON	Mold contamination underneath membrane may cause stability issues. [ ] None Present [ ] Action Taken _____ _____

NSN	**6515 Nonstandard**
PRODUCTS	Siemens Accessory Set TCPO2+TCPCPO2 Probe, intended to continuously monitor noninvasive trending of transcutaneous carbon dioxide partial pressure in any patient population and to monitor oxygen in the neonatal population when the patient is not under gas anesthesia. Recall #Z-036-0.
CODE	Part #45 27 347 EH418, Kit Lot #R006.
MANUFACTURER	Radiometer Medical A/S, Copenhagen, Denmark. Sticker labeled by: Siemens-Elema AB.
RECALLED BY	Siemens Medical Systems, Inc., Danvers, Massachusetts, by letter dated July 23, 1999. Firm-initiated recall ongoing.
DISTRIBUTION	International.

QUANTITY	17 kits were distributed.
REASON	Mislabeled -tcpO2 membrane kits labeled as tcpO2/tcpCO2 membrane kits. [ ] None Present [ ] Action Taken _____ _____
NSN	**6515 Nonstandard**
PRODUCTS	Jupiter PTA Balloon Catheters: a) Catalog #436502S; b) Catalog #436452S. Recall #Z-060/061-0.
CODE	Lot Numbers: a) A0699798; b) A0699797.
MANUFACTURER	Cordis Corporation, Miami Lakes, Florida.
RECALLED BY	Manufacturer, by letter faxed on September 16, 1999, followed by visit. Firm-initiated recall ongoing.
DISTRIBUTION	Alabama, Michigan, Illinois, Mississippi, Iowa, District of Columbia.
QUANTITY	27 units were distributed.
REASON	The outer carton was mislabeled with incorrect dimensions on side panel. [ ] None Present [ ] Action Taken _____ _____
NSN	**6525 Nonstandard**
PRODUCTS	Radiographic Film Cassettes with Intensifying Screens for Mammography: a) MIN-R 2 Cassette with MIN-R Screen, Catalog Nos. 7087984 and 1821149 (18 X 24 cm); b) MIN-R 2 Cassette with MIN-R Screen, Catalog Nos. 7091614 and 8410078 (24 X 30 cm); c) MIN-R 2 Cassette with MIN-R 2000 Screen, Catalog Nos. 8104101 and 8928392 (18 X 24 cm); d) MIN-R 2 Cassette with MIN-R 2000 Screen, Catalog No. 8999492 (24 X 30 cm); e) MIN-R 2 Cassette with MIN-R 2190 Screen, Catalog Nos. 1260579 and 1650605 (18 X 24 cm); f) MIN-R 2 Cassette with MIN-R 2190 Screen, Catalog Nos. 8910853 and 8851651 (24 X 30 cm). Recall #Z-029/034-0.
CODE	Case label: 139YY through 214YY.
MANUFACTURER	Eastman Kodak Company, Rochester, New York.
RECALLED BY	Manufacturer, by letter dated August 10, 1999. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide and international.
QUANTITY	7,105 cassettes/screen systems were distributed.
REASON	The above-referenced cassettes potentially cause a small density variation of approximately 0.3 overall density between mammography films due to a change in supply of a small plastic strip that keeps the cassette foam in place. [ ] None Present [ ] Action Taken _____ _____
NSN	**6540 Nonstandard**
PRODUCTS	FreshLook DuraSoft Phemfilcon A 45%, water 55% Toric Contact Lenses for Astigmatism with Handling Tint; individually packaged sterile contact lenses for disposable or frequent replacement programs. Recall #Z-040-9.
CODE	Lot 081513 EXP 02/01 and 081514 EXP 02/01.
MANUFACTURER	Wesley Jessen Corporation, Des Plaines, Illinois.

RECALLED BY Manufacturer, by letter dated September 30, 1999. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and Canada.
QUANTITY 873 lenses were distributed.
REASON Lenses were labeled with an axis of 90 degrees when they actually have an axis of 180 degrees.
[ ] None Present
[ ] Action Taken _____

NSN **6540 Nonstandard**
PRODUCTS Nikon Children's Eyewear Frames in various colors, Model KD5303. Recall #Z-072-0.
CODE Lot #N16134.
MANUFACTURER Nikon Optical Company, Ltd., Tokyo, Japan.
RECALLED BY Nikon, Inc., Melville, New York, by telephone or visit in March 1999, or by mail on March 18, 1999. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and Puerto Rico.
QUANTITY 198 units were distributed.
REASON The rubberized end of the earpiece may separate from the frame exposing the metal support rod that runs through the earpiece.
[ ] None Present
[ ] Action Taken _____

NSN **6550 Nonstandard**
PRODUCTS Total B-hCG Controls, for in-vitro diagnostic use. Recall #Z-037-0.
CODE List #9C21-10; Lot #53784Q100 EXP 12/23/99.
MANUFACTURER Abbott Health Products, Inc., Barceloneta, Puerto Rico.
RECALLED BY Manufacturer, by letter dated September 24, 1999. Firm-initiated recall ongoing.
DISTRIBUTION Nationwide and international.
QUANTITY 3,445 kits were distributed.
REASON Control values are greater than the package insert ranges with AxSYM or IMx systems.
[ ] None Present
[ ] Action Taken _____

NSN **6550 Nonstandard**
UPDATE Stratus Cardiac Troponin I Fluorometric Enzyme Immunoassay, Recall #Z-1257/1258-9, recalled by Dade Behring, Inc., which appeared in the September 29, 1999 Enforcement Report should read: REASON: Product may produce false positive and false negative test results.
[ ] None Present
[ ] Action Taken _____
